

## **EMITASOL™ (Diabetic Gastr paresis) Nasal Spray Project Review Meeting**

**Location:** Shire Laboratories Inc.  
1550 East Gude Drive  
Rockville, MD 20850  
(301) 838-2500

**Date:**

**Time:** 9 - 10 AM: Shire-Roberts / Shire personnel only  
10 - 4 PM: All attendees  
4 - 5 PM: Shire-Roberts / Shire personnel only (Wrap-up)

**Attendees:**

<b>Shire-Roberts:</b>	E. Bauer, D. Blanset, D. Eickhoff, T. Geary, A. Howard, M. Kabadi, P. Lang, B. Onbas, M. Petrone
<b>Shire Canada:</b>	R. Coates, R. Lim, J. Salmon, G. Thompson
<b>Shire:</b>	S. Browne, S. Geroux, L. Tiemeier, S. Tulloch, Y. Zhang
<b>Quintiles:</b>	A. Boss, N. Nanavati, G. Ross, J. Sheets, E. Torning,
<b>GloboMax:</b>	S. Bigora, C. Trapnell
<b>Questcor:</b>	A. Retzios

**Purpose:** To review entire project as part of transition to Shire .

**1) Pharmaceutical Development (M. Kabadi)**

- a) Formulation Development
- b) Stability
- c) Issues/Proposals

**2) Non-clinical Tox Studies (D. Blanset)**

- a) Review of tox data (monkey/rabbit) with the old RiboGene formulation
- b) Monkey study results and reports (New formulation)
- c) Issues/Proposals

**3) Historical PK-PD Studies (GloboMax)**

- a) Status of studies and reports
- b) Issues/Proposals

**4) Clinical Studies (E. Bauer)**

- a) Phase II PK/Safety study update and final reports (GloboMax)
- b) Phase III Clinical Efficacy/Safety studies status and final reports (Quintiles)
- c) Investigators meeting review (Quintiles)
- d) Issues/Proposals

- 5) **Manufacturing - Clinical Supplies and Registration batches (R. Coates, J. Salmon, G. Thompson)**
  - a) Clinical supplies (active and placebo) manufacturing/release status
  - b) Registration and scale-up batches for physician samples and commercial product
  - c) Stability Magellan and at Shire Canada
  - d) Issues/Proposals
- 6) **Quality Control/Quality Assurance (B. Onbas/J. Salmon)**
  - a) Audit API Manufacturer (VIS)
  - b) Issues/Proposals
- 7) **IND/NDA Submission (D. Eickhoff/A. Howard)**
  - a) IND filing status – for US and Canadian studies
  - b) NDA filing status.
  - c) Issues/Proposals
- 8) **Project Management (Mohan Kabadi)**
  - a) Review of time-line to NDA for diabetic gastroparesis
- 9) **Discussion (All)**
  - a) Adequacy of NDA package
  - b) Other studies and/or indication (e.g. delayed-emesis)
  - c) Budget - spent and available for diabetic gastroparesis (T. Geary)

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Visitors to Shire may fly into BWI, Dulles or National (Reagan) Airport.  
Hotels in the area are:

- Doubletree, Rockville Parkway, Rockville, MD  
(301) 468-1100
- Marriot Washingtonian, 9571 Washington Blvd., Gaithersburg, MD  
(301) 590-0044

**\*GROUND TRANS. AND DIRECTIONS WILL BE PROVIDED BY SHIRE \***  
Please contact Reginald Johnson at (301) 838-2500 – ext. 2581